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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,485	04/23/2001	Rocky Barry Bigbie	AM100123	5730

25291 7590 09/19/2002

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PATENT LAW GROUP  
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MADISON, NJ 07940

EXAMINER
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SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/19/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

File 607  
Application No.

09/840,485

Applicant(s)

BIGBIE ET AL.

Examiner

Khatol S Shahnan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/27/2001, 4/19/2002 and 7/10/2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. Applicants' amendment A received December 27, 2001, paper 6 is acknowledged. Claims 23-25 were canceled without prejudice. Claim 1 was amended.
2. Applicants' supplemental IDS received December 27, 2001, paper 5 is acknowledged. The references are considered by the examiner see attached PTO form 1449.
3. Applicants' response to the notices of non-compliant amendments mailed 3/25/2002 and 6/20/2002 are acknowledged. Marked -up copies of the amendments had been forwarded to the office.
4. Claims 1-22 are pending and under consideration.

#### ***Prior Citations of Title 35 Sections***

5. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

#### ***Prior Citations of References***

6. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 has been submitted with this office action.

#### ***Objections Withdrawn***

7. Objections made in paragraphs 3 and 4 of the office action mailed 9/25/2001, paper # 4 is withdrawn. Amendments to the abstract and specification are now entered because marked -up copies had been forwarded to the office.

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***Rejections Moot***

8. Rejection of claim 23 made under 35 USC 112-first paragraph in paragraph 5 of the office action mailed 9/25/ 2001, paper 4 is moot in view of applicants' cancellation of the claim.

9. Rejections of claims 23-25 made under 35 USC 102(b) in paragraphs 9 and 10 of the office action mailed 9/25/ 2001, paper 4 are moot in view of applicants' cancellation of the claims.

***Rejections Withdrawn***

10. Rejection of claims 1,3-11 2 made under 35 USC 102(b) in paragraph 6 of the office action mailed 9/25/ 2001, paper 4 is withdrawn in view of applicants' amendments.

11. Rejection of claim 2 made under 35 USC 102(b) in paragraph 7 of the office action mailed 9/25/ 2001, paper 4 is withdrawn in view of applicants' amendments.

12. Rejection of claims 12-22 made under 35 USC 102(b) in paragraph 8 of the office action mailed 9/25/ 2001, paper 4 is withdrawn in view of applicants' amendments.

13. Upon further consideration by the examiner it is determined that several distinct inventions are included in the claims and therefore a restriction requirement is deemed necessary.

***Restrictions***

14. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14 are, drawn to an immunogenically active component and a single component vaccine, classified in class 424, subclasses 130.1 and 269.1.
- II. Claims 15-17 are, drawn to a multi component vaccine, classified in class 424, subclass 183.1.

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III. Claims 18-22 are, drawn to a method of preventing disease, classified in class 534, subclass 7.22.

The inventions are distinct, each from the other because of the following reasons:

Groups I-II are drawn to structurally and functionally different products. The inventions are shown to be distinct because they are drawn to distinct products, made by different methods and they are physically and functionally distinct molecules.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case antiparasitic agents can be used to treat or prevent EPM.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Election***

14. This application contains claims directed to the following patentably distinct species of the claimed invention:

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If applicants elect group I, then there are additional election of species

Please choose one of the species from a-g.

- a) a merozoite antibody inducing inactivated *Sarcocystis neurona* cells
- b) a tachyzoite antibody inducing inactivated *Neospora hughesi* cells
- c) a merozoite antibody inducing antigen from cells
- d) a tachyzoite antibody inducing antigen from cells
- e) DNA from cells inducing merozoite antibody response
- f) DNA from cells inducing tachyzoite antibody response
- g) mixture- elect two from a-f

If applicants elect group II, then there are additional election of species

Please choose one of the species a-b

- a) elect one first component and one second component or
- b) elect two components for mixture for first component and two components for mixture for second component

If applicants elect group III, then there are additional election of species

- a) a merozoite antibody inducing inactivated *Sarcocystis neurona* cells
- b) a tachyzoite antibody inducing inactivated *Neospora hughesi* cells
- c) a merozoite antibody inducing antigen from cells
- d) a tachyzoite antibody inducing antigen from cells
- e) DNA from cells inducing merozoite antibody response
- f) DNA from cells inducing tachyzoite antibody response
- g) mixture- elect two from a-f

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h) elect one first component and one second component or

i) elect two components for mixture for first component and two components for mixture  
for second component

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 15 and 18 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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***Conclusion***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30 AM - 4 PM from Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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September 12, 2002

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600